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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/557,011 04/20/00 RANGANATHAN

N KBI-0003

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EXAMINER

PATTEN, P

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

01/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/557,011

Applicant(s)

Ranganathan et al.

Examiner

Patricia Patten

Group Art Unit

1651



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-7 is/are pending in the application.

Of the above, claim(s) 5-7 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-4 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I, Claims 1-4 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search for Group II would not be an undue burden on the examiner since the examiner had already performed a prior art search and discovered that urease had been used to treat uremia. This is not found persuasive. The showing that urease, a compound which is not claimed can perform the same function as the instantly claimed invention is indication that there may be a myriad of compounds which also perform the same function. Thus, a search for the method would not necessarily bring about prior art pertaining to the composition as Instantly claimed. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites 'middle molecular weight molecules.' This statement is indefinite. There are a myriad of middle molecular weight molecules in the body, and one of ordinary skill in the art would have trouble ascertaining what middle molecular weight molecules the claim is referring to.

Limitation to particular molecules is suggested in order to avoid confusion.

Applicants argument filed 11/07/2000 was considered but is not persuasive.

Applicants argue that the Specification clearly teaches 'middle molecular weight molecules' which would be advantageous in the composition of the present invention, and that one of ordinary skill in the art would understand that the claim, read in light of the specification, would necessarily indicate the use of specific 'middle molecular weight' molecules as described in the Instant disclosure. However, the term 'middle molecular weight molecules' in the claim is so broad that it may encompass a myriad of molecules which is outside of the scope of the claimed invention. The meets and bounds of the claim upon the recitation of 'middle molecular weight molecules' is thereby non-delineating and vague.

*Cite in re Bates from MPEP
incorp of limits from Spec improper*

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yatzidis et al. (1979) in view of Prakash et al. (1995) and further in view of Goldenhersh et al. (1976). Claims 1-4 are drawn to a microencapsulated formulation comprising a mixture of sorbents and a bacterial source, wherein the sorbents have absorption affinities for substances such as ammonia, urea, creatine, phenols and indoles. Claims are further drawn to where the composition comprises a phosphate binding agent and a water binding agent.

Yatzidis et al. (1979) disclosed that locust bean gum showed a beneficial effect on patients with renal failure (uremia). Locust bean gum was shown to have the ability to absorb urea, creatine, uric acid, ammonia phosphorus, chloride and sodium (pp.105). Locust bean gum also 'adsorbs about 10 times its own weight in water' (instant specification pp.4, lines 14-15). Yatzidis et al. did not specifically mention the combination of locust bean gum with a bacterium.

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Prakash et al. (1995) disclosed a method for treating uremia by use of a microencapsulated E.coli strain (DH5) (Please see Abstract). They explained that the E.coli cells 'efficiently depleted urea' (pp.625 Col.1)) and further indicated that the same bacteria lowered overall ammonia levels (pp.625 Col.2).

Goldenherh et al. (1976) discovered that there was a severe 'adsorption competition which interfered with adsorption of creatine on activated carbon'(pp.252 Col.2). They consequently found that a microencapsulated form of activated charcoal resulted in required less of an amount of the charcoal being administered (pp.253, Col.1).

Applicants arguments filed 11/7/2000 were considered, but were not found persuasive.

Applicants argue the references separately, indicating that none of the references provide motivation to combine the instantly claimed ingredients.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Here, the Examiner is relying upon case law in order to establish a prima facie case of obviousness. Although the references themselves may not indicate a motivation to combine the Instantly claimed ingredients, the MPEP states 'The rationale to modify or combine the prior art

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does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law (MPEP 2114).

Because all of the instantly claimed ingredients were known in the art for treating uremia separately, one of ordinary skill in the art would have had a reasonable expectation that the combination of the ingredients would have provided an additive affect on the ailment of uremia. As stated in the Office Action dated 8/01/2001: It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art to treat uremia. This rejection is based on the well established proposition of patent law that **no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518.**

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

One of ordinary skill in the art would have been further motivated to have microencapsulated the composition comprising bacteria and absorbents because microencapsulation would have resulted in a lesser quantity of absorbents being used due to

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inhibitory mechanisms as discussed by Goldenhersh et al. It was further known that microencapsulated bacterium had a longer lasting effect as taught by Prakash et al. Hence, the ordinary artisan would have reasonably ascertained that a formulation for treating uremia had an improved beneficial effect when it was microencapsulated due to the competitive aspects in biological fluid.

No Claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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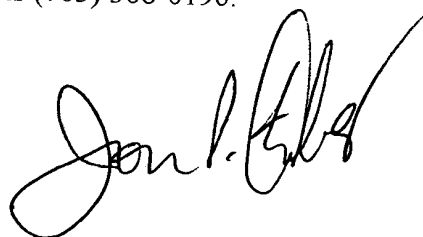
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Patricia Patten, whose telephone number is (703)308-1189. The examiner can normally be reached on M-F from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Jon P. Weber". The signature is fluid and cursive, with a large loop at the end.

Jon P. Weber, Ph.D.
Primary Examiner